Supplementary participant information leaflet for people who have recovered capacity

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PLINTH
PLATFORM STUDY FOR INTRACEREBRAL HAEMORRHAGE

Funded by:

CHIEF SCIENTIST OFFICE

Your research team is from:

NHS Lothian

Scan for the PLINTH video

We invite you to consider more information about what's involved in the PLINTH feasibility study to help you decide whether to take part

Thank you for considering the short participant information that was provided about the PLINTH feasibility study. This leaflet provides more information about the study. It may take you about 15 minutes to read it. Do ask if anything is unclear. You can find information about how to contact us at the end of this leaflet. Please feel free to talk to your nearest relative or friends about this research study if you wish. Joining this research study is entirely up to you. Your decision will not affect the standard medical care that you receive.

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What's happened so far?

You've already met one of our team of doctors and nurses who specialise in caring for people with stroke due to bleeding in the brain, known as 'intracerebral haemorrhage' or 'brain haemorrhage'. We do research that aims to improve care for people with brain haemorrhage.

Your welfare attorney, welfare guardian or nearest relative previously agreed to you taking part in the PLINTH feasibility study. You've been given a brief summary of this PLINTH feasibility study to help you decide whether you would like to continue to take part.

What's next?

We would like to share some information that is tailored to you about:

- Brain haemorrhage
- Your care so far and options for your care in future
- What's involved in this study

We'll do this using something called Tailored Talks, which can share this information in a document on screen, on paper, or in an email.

What's involved in this study?

We are doing this study at three hospitals in two regions of Scotland: the Royal Infirmary of Edinburgh in Lothian and Monklands and Hairmyres hospitals in Lanarkshire.

We will find people who are first diagnosed with brain haemorrhage between 1 October 2023 and 30 June 2025 by searching medical records,

brain scans, and referrals to stroke services. During this time, we expect to involve roughly 170 people in Lothian and 70 people in Lanarkshire.

We will include people:

- Who live in Scotland
- Who are aged 18 years or older when diagnosed with brain haemorrhage
- Whose brain haemorrhage is most likely to be caused by small vessel disease in the brain (in other words, age-related wear and tear of the small blood vessels)
- Who survive the brain haemorrhage
- Who have several options for at least one aspect of the future care of their brain haemorrhage

We will not include anyone whose hospital doctor thinks it is inappropriate for us to approach about the research study.

We will ask for consent to join the study from the person with brain haemorrhage, or from their nearest relative if the person cannot consent for themselves. We will ask for your consent to keep you in the study if you lose mental capacity to make decisions for yourself in future.

What would taking part involve?

You will receive standard care for brain haemorrhage, whether or not you choose to take part. In addition to standard care:

- **We'll give you more detailed information that is tailored to you** about

brain haemorrhage, your care, and this study. This information can be shared on screen, on paper, or by email. It will cover the type of brain haemorrhage, the care you have received, options for your care, and whether you would be willing to consider taking part in a future platform study of the options for your care. There's no obligation to be part of a future study.

- **We'll gather information** from your medical records and keep it confidential in a secure database.
- **We'll interview** you or your nearest relative twice, for around 15 minutes **at 3 days and at 14 days** after you give consent. We will ask you a few questions about a PLatform study for INTracerebral Haemorrhage, known as PLINTH for short. Platform studies allow several options for brain haemorrhage care to be investigated in one study. This means that they are more inclusive and they can help find which option is best faster than other types of study. We want to interview you to work out whether a platform study for people with brain haemorrhage can be done.
- We'll ask whether you or your nearest relative could complete a short survey about quality of life after brain haemorrhage.
- **We'll monitor your health records** confidentially to see how you get on after you leave hospital.

What are the possible benefits of taking part?

- We'll provide you with information about brain haemorrhage so that you may learn more about your health.

- You will have the opportunity to ask questions and have them answered by a brain haemorrhage specialist.
- We will check how you get on. You may feel supported by this.
- We can send you a summary of the results at the end of the study.
- The results of this study will help us to design research studies for people with brain haemorrhage in the future.

What are the possible disadvantages and risks of taking part?

- There is a low risk that you may find the information about brain haemorrhage distressing. The clinical and research team are experienced and sensitive and they will support you.
- There is an extremely low risk that the confidential information that we hold from your medical records is shared unintentionally, or due to a cyberattack. We use strong security to protect the database storing your information. Research staff have training in information security.
- You may find the time you spend being interviewed inconvenient or tiring. We will go at your own pace and we can talk to your nearest relative instead.

This study should have no impact on your insurance. We do not foresee any chance of commercial use of the results of this study. You will not be paid for taking part.

Further supporting information

What to expect during the consent process. We will give you time to consider information about the study. You will have the opportunity to

ask questions and have them answered. You can take as long as you need to decide whether to take part. If you want to take part, we will ask you or your nearest relative to sign a consent form.

Informing your general practitioner. We will ask your clinical team to tell your general practitioner that you are taking part in this study. We will not share with them any of the information you provide for the study.

What if something goes wrong? If you have a concern about any aspect of this study, please contact the Chief Investigator using the contact details on the last page of this leaflet, who will do his best to answer your questions. Alternatively, speak to the independent advisor, whose telephone number is at the end of this leaflet. If you remain unhappy and wish to complain formally, you can do this by contacting NHS Lothian Patient Experience Team. In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). The contact for complaints in your NHS region is: NHS Lothian Patient Experience Team, Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG. Telephone 0131 536 3770. Email: feedback@nhslothian.scot.nhs.uk . Members of the public in Scotland have their rights and responsibilities set out in the Patients Rights (Scotland) Act 2011.

What will happen if I don't want to carry on with the study? Your

decision to take part in the PLINTH feasibility study is entirely voluntary. You are free to withdraw from all or part of this study at any time, without giving a reason. Any decision to withdraw will not affect the standard medical care that you receive. We will ask for your consent to keep and use any information collected about you up to the point of exit from the study should you decide to withdraw.

How will my information be handled and kept confidential? PLINTH is run by a team at NHS Lothian and the University of Edinburgh who process your information and take care to protect it. The team includes medical, nursing, computing and administrative staff, all of whom have a duty of confidentiality to you. Your information will be stored on secure University of Edinburgh servers, in a database that can only be accessed with a valid username and password. We comply with the GDPR and Data Protection Act 2018 and Caldicott principles when sharing or processing your data within the NHS and other organisations involved in the research. The University of Edinburgh and NHS Lothian are the data controllers for the study. You have the right to check the accuracy of information held about you and correct any errors.

During the study we will collect your contact information (address, telephone, email address) and the contact information of your nearest relative, power of attorney or welfare guardian in order to contact you about the study. We will collect some identifiable data (name, date of birth, CHI Number) to allow us to link to your health records later on. We will also collect medical information from your medical notes in relation

to your brain haemorrhage, what treatment you receive for it, and any other conditions or medications you may have.

We will access information about how you are getting on from the National Records of Scotland and the Information Services Division of NHS Scotland. We will identify you when we communicate with your GP, to make sure that we are communicating about the correct person. Hospitals involved in PLINTH may be required to provide information for official inspections of research conduct made by the sponsor of the study or other regulatory bodies.

All identifying information will be removed before the data are analysed. We will not identify you in the report of the study's results that we submit to a medical journal.

Sharing data with other researchers is important for several reasons: this ensures that research is open to peer scrutiny, optimises the use of good quality research data, supports policy and other decision-making, and allows researchers to explore whether new ideas during or after the study might be true by re-examining data. Therefore, we may share anonymous information from PLINTH with other researchers anywhere in the world, to help answer related research questions. Other countries might not offer the same level of protection of peoples' privacy as that demanded by law in the UK, so we will always ensure that other researchers will not be able to identify you from the information that we share. We do not plan to ask for further ethics committee approval for each re-use of data.

What will happen to the results of this study? There will be a newsletter about the results which you can choose to have sent to you. The results of the study will be submitted for publication in scientific journals. We will also make the results available in a format appropriate to the general public on our website.

Who is organising and funding this study? The University of Edinburgh and NHS Lothian sponsor the research. The Chief Scientist Office of the Scottish Government's Health Department funds the study via a grant paid to The University of Edinburgh. Professor Rustam Al-Shahi Salman is the Chief Investigator.

How have patients and the public been involved in this study? Brain haemorrhage survivors were involved in identifying the PLINTH feasibility study as a priority. A brain haemorrhage survivor has helped to design the study and was part of the team who applied for funding from the Scottish Government. The Research to Understand Stroke due to Haemorrhage (RUSH) patient reference group will monitor the progress of the study. You can find information about the RUSH patient reference group here: www.RUSH.ed.ac.uk.

Who has reviewed this study? All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Scotland A Research Ethics Committee. All participants are covered by insurance required to be in place before the study starts.

What if relevant new information becomes available? If new information becomes available which might influence whether you should continue to take part in the study, we will contact you.

What happens when the research stops? Anonymised information about you will be kept indefinitely so that researchers can look at it again. For regulatory reasons, information about your participation will be archived at your local hospital and at the PLINTH study office for five years.

Who to contact for more information about the study

You can contact the PLINTH research team if you have questions:

RUSH, Centre for Clinical Brain Sciences, Chancellor's Building, Edinburgh Royal Infirmary, 49 Little France Crescent, Edinburgh. EH16 4SB. Telephone helpline: 0131 537 2944.

You can contact your local team about your participation:

Professor Rustam Al-Shahi Salman, honorary consultant neurologist. Centre for Clinical Brain Sciences, Chancellor's Building, 49 Little France Crescent, Edinburgh. EH16 4SB. Telephone: 0131 537 2944.

You can obtain independent advice about this study by contacting:

Dr Sarah Keir, consultant stroke physician. Stroke Unit, Western General Hospital, Crewe Road South, Edinburgh. EH4 2XU. Telephone: 0131 465 9102.